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## NOTICE OF ALLOWANCE AND FEE(S) DUE

34055 7590 02/06/2009

PERKINS COIE LLP  
POST OFFICE BOX 1208  
SEATTLE, WA 98111-1208

EXAMINER

LIU, SAMUEL W

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 02/06/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/761,717

01/20/2004

Yukun Sun

57783.8004.US00

3780

TITLE OF INVENTION: METHOD OF PRODUCING INSULINOTROPIC GLP-1 (7-36) POLYPEPTIDE AND/OR GLP-1 ANALOGS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	05/06/2009

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

34055 7590 02/06/2009

PERKINS COIE LLP  
POST OFFICE BOX 1208  
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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/761,717 01/20/2004 Yukun Sun 57783.8004.US00 3780

TITLE OF INVENTION: METHOD OF PRODUCING INSULINOTROPIC GLP-1 (7-36) POLYPEPTIDE AND/OR GLP-1 ANALOGS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional YES \$755 \$300 \$0 \$1055 05/06/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
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LIU, SAMUEL W 1656 435-440000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 \_\_\_\_\_
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 \_\_\_\_\_
- 3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/761,717	01/20/2004	Yukun Sun	57783.8004.US00	3780
34055	7590	02/06/2009	EXAMINER	
PERKINS COIE LLP POST OFFICE BOX 1208 SEATTLE, WA 98111-1208			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1656	
DATE MAILED: 02/06/2009				

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/761,717	SUN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SAMUEL W. LIU	1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/15/09 & 1/29/09.
2. ☒ The allowed claim(s) is/are 1-7,9-14,16 and 37.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| <p>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</p> <p>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material</p> | <p>5. <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____.</p> <p>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</p> <p>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</p> <p>9. <input type="checkbox"/> Other _____.</p> |
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### **DETAILED ACTION**

The amendment filed 1/15/09 which amends claims 1, 4-7, 9-12, 37 and 39, and cancels claims 8, 15, 17-36 and 38 has been entered. The applicants' request filed 1/15/09 for extension of time of one month has been entered. The Office action (Final) mailed 9/15/08 is withdrawn. Claims 1-7, 9-14, 16, 37 and 39 are examined in this Office action.

Applicants' claim for foreign priority under 35 U.S.C. 119 (a)-(d) is acknowledged; the certified copy of the China CN2001/126278 has been received 11/13/08 and considered.

### **EXAMINER'S AMENDMENT**

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with the applicants' representative Michael Wise on 1/29/09. Applicants agree to the Examiner's proposed amendment to claims 1 and 37, and agree to cancel claim 39.

#### **Amendments to the claims:**

Claim 1 (*Currently amended*). A method of producing insulinotropic GLP-1 (7-36) polypeptide and/or GLP-1 analogs comprising:

(a) introducing into a DNA fragment a first and second individual restriction endonuclease cleavage sites capable of forming a hybrid site to two terminals of a gene which encodes either the GLP-1(7-36) polypeptide or GLP-1 analogs, respectively, and a [-] third restriction endonuclease cleavage site located outside of the region between said first and second restriction endonuclease cleavage sites, wherein the second restriction endonuclease cleavage site is located between the first and third restriction endonuclease cleavage sites;

(b) digesting the DNA fragment of step (a) with restriction endonucleases at the first and third restriction endonuclease cleavage sites and ligating said digested DNA fragment with a vector, wherein said vector has the second and third restriction endonuclease cleavage sites and is digested at said second and third restriction endonuclease cleavage sites before said ligation;

(c) repeating step (b) to form an expression vector comprising N copies of GLP-1(7-36) gene, GLP-1 analog gene, or a combination of GLP-1(7-36) gene and GLP-1 analog genes, wherein N is an integer from 2 to 32;

(d) transforming said expression vector into a host cell;

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- (e) expressing in the host cell a protein comprising N copies of the GLP-1(7-36) polypeptide, GLP-1 analog, or the combination thereof, but without any carrier protein;
- (f) breaking up the host cell and cleaving said protein of step (e) under conditions wherein the cleavage does not occur at the peptide bonds adjacent to internal lysine residues to obtain GLP-1(7-36) polypeptides or GLP-1 analogs that are capable of stimulating the secretion of insulin; and
- (g) separating and purifying said GLP-1 (7-36) polypeptides or GLP-1 analogs.

Claim 37 (*Currently amended*). A method of producing insulinotropic GLP-1 (7-36) polypeptide and/or GLP-1 analogs comprising:

- (a) introducing into a DNA fragment a first and second individual restriction endonuclease cleavage sites capable of forming a hybrid site to two terminals of a gene which encodes either the GLP-1(7-36) polypeptide or GLP-1 analogs, respectively, and ~~an~~ a third restriction endonuclease cleavage site located outside of the region between said first and second restriction endonuclease cleavage sites, wherein the second restriction endonuclease cleavage site is located between the first and third restriction endonuclease cleavage sites;
- (b) digesting the DNA fragment of step (a) with restriction endonucleases at the first and third restriction endonuclease cleavage sites and ligating said digested DNA fragment with a vector, wherein said vector has the second and third restriction endonuclease cleavage sites and is digested at said second and third restriction endonuclease cleavage sites before said ligation;
- (c) repeating step (b) to form an expression vector comprising N copies of GLP-1(7-36) gene, GLP-1 analog gene, or a combination of GLP-1(7-36) gene and GLP-1 analog genes, wherein N is an integer from 2 to 32;
- (d) transforming said expression vector into a host cell;
- (e) expressing in the host cell a protein comprising N copies of the GLP-1(7-36) polypeptide, GLP-1 analog, or the combination thereof, but without any carrier protein;
- (f) breaking up the host cell and cleaving said protein of step (e) under conditions wherein the cleavage does not occur at the peptide bonds adjacent to internal lysine residues to obtain GLP-1(7-36) polypeptides or GLP-1 analogs that are capable of stimulating the secretion of insulin.

Cancel claim 39.

*The following is an examiner's statement of reasons for allowance:*

The 112/2 rejection of claims 1-7, 9-14, 16 and 37-39 is withdrawn in light of the amendment (filed 1/15/09) of the claims thereof, and in light of cancellation of claim 38. The

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112/1 rejection (new matter) of claims 1-7, 9-14, 16 and 37-39 is withdrawn in light of the amendment (filed 1/15/09) of the claims and cancellation of claim 38, and in light of that the specification as originally filed has supports for “N is an integer from 2-32” (p.5, line 14) and for “third restriction endonuclease cleavage site” (p.5, lines 1-14). The 112/1 rejection (scope enablement) of claims 1-7, 9-14, 16 and 37-39 is withdrawn in light of the Examiner proposed amendment above which applicants agree (see above), and in light of cancellation of claim 38.

Therefore, claims 1-7, 9-14, 16 and 37 are allowed.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weber Jon, can be reached at (571) 272-0925. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

/Samuel W. Liu/

Examiner, Art Unit 1656

January 29, 2009

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657/6